K100704

MAY 14 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter

Submitted by:

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United States Contact Person:

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Date Prepared: April 12, 2010

Device name

Proprietary name: ACCU-CHEK® FlexLink Plus infusion set
Common name: subcutaneous infusion set
Classification name: intravascular administration set
Product Code: FPA

Proprietary name: ACCU-CHEK® LinkAssist Plus insertion device
Common name: infusion set insertion device
Classification name: syringe needle introducer
Product Code: KZH

Predicate device

We claim substantial equivalence to the current legally marketed ACCU-CHEK® Ultraflex infusion set and ACCU-CHEK® LinkAssist insertion device.

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510(k) Summary, Continued

Device description

The ACCU-CHEK® FlexLink Plus is a disconnectable infusion set with soft cannula perpendicular to the adhesive, for transfusion of insulin into the subcutaneous tissue. The unit is designed to interface with commercially available insulin infusion pumps with suitable connections. The insulin infusion pump systems are designed to control the delivery of insulin as prescribed by a health care professional. The system (infusion set, insulin infusion pump, and insulin) is indicated for patients with insulin dependent diabetes mellitus.

The ACCU-CHEK® LinkAssist Plus is an insertion aid for automatic application of ACCU-CHEK® infusion sets equipped with a compatible adapter. The ACCU-CHEK® LinkAssist device is non-invasive, non-sterile and intended for multiple uses by the same patient.

Intended use

ACCU-CHEK® FlexLink Plus is an infusion set for the subcutaneous infusion of insulin administered with micro dosage insulin pumps.

ACCU-CHEK® LinkAssist Plus is an insertion device, which is intended specifically for placement of compatible ACCU-CHEK® FlexLink Plus infusion sets.

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510(k) Summary, Continued

Device Comparisons

The ACCU-CHEK® FlexLink Plus infusion set was compared to the ACCU-CHEK® Ultraflex infusion set. The ACCU-CHEK® FlexLink Plus is substantially equivalent to this product by having the same intended use, same storage conditions, same luer connector, same operating conditions, a flexible catheter and needle for insertion into the subcutaneous tissue and separate extension tubing with detachable connector. Both sets have an adhesive patch that secures the headset to the skin. Prior to infusion, both sets require removal of the introducer needle. The ACCU-CHEK® FlexLink Plus incorporates a needle protection feature that retracts the needle automatically following insertion of the needle and cannula.

The optional ACCU-CHEK® LinkAssist Plus insertion device was compared to the optional ACCU-CHEK® LinkAssist insertion device. The ACCU-CHEK® FlexLink Plus is substantially equivalent to this product by having the same intended use, same storage conditions, same operating conditions, and same general functionality. The overall dimensions of the ACCU-CHEK® FlexLink Plus are slightly wider and longer than the ACCU-CHEK® FlexLink device. Both devices include a safety catch; the ACCU-CHEK® FlexLink Plus incorporates the safety catch in the base of the device such that it is depressed when placing the device into position on the body.

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Summary of Studies

Functional Testing:

In vitro functional testing of the ACCU-CHEK® FlexLink Plus infusion set and the optional ACCU-CHEK® LinkAssist Plus insertion device was conducted. Biocompatibility testing was performed on the materials used in both devices.

Clinical Studies:

Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the ACCU-CHEK® FlexLink Plus infusion set or the optional ACCU-CHEK® LinkAssist Plus insertion device.

System validation testing included human factors usability testing of the customer requirements and primary operating function of the ACCU-CHEK® FlexLink Plus infusion set and the optional ACCU-CHEK® LinkAssist Plus insertion device. Individuals who participated in the evaluation included patients who routinely use an insulin pump and infusion set. The usability evaluations determined the customer requirements were met and that the primary operating function operated as intended. No needle stick injuries were reported associated with unintentional ejection.

Study Conclusions

Functional Testing:
The results of the testing conducted indicate the ACCU-CHEK® FlexLink Plus infusion set and the optional ACCU-CHEK® LinkAssist Plus insertion device functioned according to specifications and the materials used in the devices are biocompatible.

Human factors usability testing:
The design validation of ACCU-CHEK® FlexLink Plus & ACCU-CHEK® LinkAssist Plus confirmed that the devices fulfill its intended use, customer requirements and primary operating functions.

Based upon these results, the product is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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MAY 14 2010

Re: K100704
Trade/Device Name: ACCU-CHEK® FlexLink Plus infusion set with optional ACCU- CHEK® LinkAssist Plus insertion device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FRN
Dated: April 14, 2010
Received: April 16, 2010

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100704

Device Name: ACCU-CHEK® FlexLink Plus infusion set with optional ACCU-CHEK® LinkAssist Plus insertion device

Indications for Use:

ACCU-CHEK® FlexLink Plus is an infusion set for the subcutaneous infusion of insulin administered with micro dosage insulin pumps.

ACCU-CHEK® LinkAssist Plus is an insertion device, which is intended specifically for placement of compatible ACCU-CHEK® FlexLink Plus infusion sets.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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